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08/837,009	04/11/97	BELL	G 2300.0202

EXAMINER	
SAOUD, C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/837,009	Applicant(s) BELL et al.
	Examiner Christine Saoud	Group Art Unit 1646

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-41* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

2. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Oath/Declaration

3. The reissue oath/declaration filed with this application is defective because it fails to contain a statement that "all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration" arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414.

4. Claims 1-41 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 6-9, and 14-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions encoding insulin-like growth factors wherein the nucleic acid molecule comprises the sequence of (a) or (b) of claim 1 (including host cells containing said nucleic acid molecule, methods of making a polypeptide from said host cells), does not reasonably provide enablement for nucleic acid molecules encoding an insulin-like growth factor wherein the nucleic acid is complementary to (a) or (b), or wherein the nucleic acid is at least 18 bases in length and which "selectively hybridize to human genomic DNA encoding hIGF. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 1 is directed to a composition comprising nucleic acid molecules encoding insulin-like growth factor, wherein the nucleic acid has a sequence which is selected from a specified group. Element (c) are nucleic acid sequences which are complementary to those sequence which encode the insulin-like growth factors. Therefore, by definition, the nucleic acid molecule of part (c) of claim 1 cannot encode the polypeptide because it is complementary (i.e. non-coding) and is therefore not enabling for a composition comprising nucleic acid molecules encoding insulin-like

growth factor, as required by the claim. This is also true for claims 8 and 18, which contain this same language. Claims 6-7, 9, 14-17, 19-24, 29-31, and 36-41 are dependent from these claims, and are also, therefore, not enabled for the reasons provided above.

Claim 1 is directed to a composition comprising nucleic acid molecules encoding insulin-like growth factor, wherein the nucleic acid has a sequence which is selected from a specified group. Element (d) are fragments of (a)-(c) "that are at least 18 bases in length and which will selectively hybridize to human genomic DNA encoding hIGF. The claim is broader than the enabling disclosure because one of ordinary skill in the art would not reasonably expect a nucleic acid which is only 18 bases in length to encode an insulin-like growth factor protein. The specification only provides for two IGF proteins (IGF-I in Figure 1 and IGF-II in Figure 2). The mature forms of these proteins consist of 70 and 67 amino acids respectively, therefore, there is a minimum number of nucleic acid residues which are required to enable the instant claim because the claim is directed to compositions comprising nucleic acids encoding IGF. In addition, the instant specification fails to provide a description of "human genomic DNA encoding hIGF", and without this information, either from the instant specification or the prior art, one would not be able to practice the instant invention because one would not know if the fragment hybridized without knowing the sequence of the human genomic DNA encoding hIGF. This is also true for claims 8 and 18, which contain this same language. Claims 6-7, 9, 14-17, 19-41 are dependent from these claims, and are also, therefore, not enabled for the reasons provided above.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All of the claims are directed to nucleic acid sequences (or contain nucleic acid sequences, transformed by a DNA sequence), however, "a nucleic acid sequence" is merely a representation of one characteristic of a nucleic acid molecule. The claims are unclear and indefinite because they should be claiming the nucleic acid molecule which is the actual invention, not the sequence of the nucleic acid molecule. A nucleic acid molecule can have sequence encoding a protein, but the compound or composition which is being claimed is the physical nucleic acid molecule, not the characteristic of a specific sequence. This ground of rejection can be obviated by directing the claims to nucleic acid molecules (which comprise a sequence), transforming with a nucleic acid molecule (which comprises a sequence), etc. Please be sure to also amend the dependent claims to provide proper antecedent basis for the new language.

Claim 1 is unclear and indefinite for the recitation "comprising nucleic acid molecules containing a human sequence encoding insulin-like growth factor". The claim is indefinite because a nucleic acid molecule does not contain a sequence, but has a sequence of nucleotides or encodes an amino acid sequence. The claim is further unclear for the recitation of "encoding insulin-like growth factor" because this implies that there is a single molecule that is considered

insulin-like growth factor, when it is clear from the specification that at least two IGFs are encompassed by the claims. The claim also indicates "a human sequence", but it is not clear how the claimed sequence of the nucleic acid molecule would differ from other mammalian sequences encoding IGF. It is not clear how the limitation of "a human sequence" defines the instant invention from any other nucleic acid sequence encoding IGF, and therefore, serves as a source of confusion in the claim. Language such as "a composition comprising a nucleic acid molecule encoding an insulin-like growth factor (IGF) substantially free of nucleic acid molecules not encoding IGF, wherein the nucleic acid molecule has a sequence selected from the group consisting of ... " would be sufficient to overcome the issues of indefiniteness.

Claims 1, 8, and 18 recite fragments that are at least 18 bases in length and which will selectively hybridize to genomic DNA encoding hIGF. These claims are unclear and indefinite because the claims fail to recite any hybridization conditions, therefore, the metes and bounds of the claims cannot be determined. There are several factors which affect the hybridization of nucleic acids and there are a multitude of conditions which may provide selective hybridization because selectivity is a relative condition. Without some sort of guidance or definition of what "selectively hybridize" is meant to encompass, the metes and bounds of the instant claims cannot be determined, thereby making the claim indefinite.

Claims 1, 8, and 18 are unclear and indefinite for the recitation of "human genomic DNA encoding hIGF". This term is not defined in the instant specification or in the prior art in the sense that it is not know what DNA this is meant to encompass. Without knowing the

composition of "human genomic DNA encoding hIGF", one would not know if an 18 base fragment of the nucleic acid molecule of the claims would selectively hybridize, therefore, the metes and bounds of the claims cannot be determined.

Claims 20 and 22 recite the limitation "phigf1" and "phigf2", respectively" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 29 and 30 recite the limitation "phigf1" and "phigf2", respectively" in claim 24. There is insufficient antecedent basis for this limitation in the claim.

Claims 19-22, 29-30, and 40-41 refer to "phigf1" or "phigf2", however, the metes and bounds of these terms cannot be determined. These are terms that have been coined in the instant specification and are not well-known in the art as having any particular, defined composition (unlike human growth hormone, for example). Therefore, the metes and bounds of the claims are unclear and indefinite because it is not clear what limitation the recitation of "phigf1" or "phigf2" is meant to convey.

Claims 25-28 and 32-35 are unclear and indefinite for depending on two different claims (a method of one claim and a product of another claim). It is suggested that the claims be rewritten such that they depend from the method claim but incorporate the product language directly into the claim, rather than attempting to incorporate it by depending from a second claim.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christine Saoud, Ph.D.
April 12, 1999
CA

JOHN ULM
PRIMARY EXAMINER
GROUP 1800